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No. 86-1783

In the Supreme Court of the United States

OCTOBER TERM, 1987

JERRY J. COLAHAN, d/b/a
IBA OF OHIO, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Federal Food, Drug, and Cosmetic Act permits a defendant to challenge in an enforcement proceeding the prescription status of a drug which has been determined by the Food and Drug Administration in the course of the approval of a new animal drug application.

2. Whether the forms used by petitioners for the distribution of new animal drugs satisfied the requirement that the drugs be sold "only to or on the prescription or other order of a licensed veterinarian" (21 C.F.R. 201.105(a)(1)).

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A23) is reported at 811 F.2d 287. The memorandum opinion and order of the district court (Pet. App. A29-A48) is unreported. An earlier opinion of the court of appeals (Pet. App. A49-A57) is reported at 635 F.2d 564. An earlier memorandum opinion and order of the district court (Pet. App. A58-A66) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 5, 1987. The petition for writ of certiorari was filed on May 5, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. (& Supp. III) 301 *et seq.*, established a system of premarketing approval for new human and animal drugs.[1] 21 U.S.C. 355(a), 360b(a)(1)(A); see *United States* v. *Generix Drug Corp.*, 460 U.S. 453, 458 (1983); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612 (1973); *United States* v. *An Article of Drug Consisting of 4,680 Pails (Neo-Terra)*, 725 F.2d 976, 978 (5th Cir. 1984). The Act prohibits the introduction of a new animal drug into interstate commerce unless the Food and Drug Administration (FDA) has approved a new animal drug application (NADA) for it. 21 U.S.C. 360b(a)(1)(A); *Neo-Terra*, 725 F.2d at 980. The NADA approval process is an adjudication in which the FDA decides whether to grant a license to the sponsor[2] and under what conditions

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[1] Section 201(g) of the Act defines "drugs" to include both human and veterinary drugs. 21 U.S.C. 321(g). A drug is a "new drug" or a "new animal drug" unless it is generally recognized by experts as safe and effective for its intended uses. See 21 U.S.C. 321(w); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 613 (1973); *United States* v. *An Article of Drug Consisting of 4,680 Pails (Neo-Terra)*, 725 F.2d 976, 980 (5th Cir. 1984).

[2] NADA approvals are not generic, and the FDA's decision whether to approve a drug is not a public proceeding. Rather, the agency decides on the basis of the specific facts submitted by the sponsor whether a particular application should be approved. The pendency of an NADA is confidential, and ordinarily does not become public knowledge until the FDA approves an application and publishes the approval regulation. 21 C.F.R. 514.11(b). If the agency issues an order refusing to approve an application, only the applicant may appeal, even though the existence of the NADA becomes public

the drug will be approved (*e.g.*, whether it may be dispensed only by prescription or may be sold over-the-counter). The FDA has exclusive jurisdiction to approve or disapprove a NADA, and to impose conditions under which an approved drug may be used, which are specified in the drug's labeling. See, *e.g.*, 21 U.S.C. 360b(i); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 627.[3] If the FDA rejects a NADA because, for example, one of the proposed conditions of use (such as over-the-counter use) is unacceptable to the agency, the drug sponsor can seek an administrative hearing. 21 U.S.C. 360b (c). If the hearing proves unsuccessful, the sponsor can seek judicial review of the agency's decision in the court of appeals, but the agency's decision must be upheld if it is supported by substantial evidence. 21 U.S.C. 360b(h), incorporating 21 U.S.C. 355(h); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 625-626; *American Cyanamid Co.* v. *Young*, 770 F.2d 1213, 1218, 1220 (D.C. Cir. 1985); *Edison Pharmaceutical Co.* v. *FDA*, 600 F.2d 831 (D.C. Cir. 1979). No other firm may market a sim-

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at that time. 21 U.S.C. 360(h), incorporating 21 U.S.C. 355(h); *Bradley* v. *Weinberger*, 483 F.2d 410, 413 n.1 (1st Cir. 1973). Thus, if the agency refuses to approve an original or a supplemental application requesting over-the-counter sale of an approved prescription drug, only the sponsor can appeal the decision.

[3] When it approves a veterinary drug, FDA is required, by 21 U.S.C. 360b(i), to publish a regulation that lists, among other things, the drug's conditions of use. See 21 C.F.R. Pts. 529-555 and 558. Not all of the approvals of the fifteen drugs in issue here are so listed, because 21 U.S.C. 360b(i) did not become effective until 1969, after some of the approvals had been granted. Some, but not all, of the pre-1969 approvals have since been listed.

ilar drug without a separate approval, and no other firm may rely in support of an application upon the data submitted by a prior sponsor. 21 C.F.R. 514.1(a).

The FDCA also prohibits any person from introducing into interstate commerce any human or veterinary drug that is "misbranded." 21 U.S.C. 331(a). To avoid being deemed misbranded, Section 502(f) of the FDCA, 21 U.S.C. 352(f), requires that drugs bear "adequate directions for use," which means adequate directions for use by laymen. 21 C.F.R. 201.5. A proviso to Section 502(f), however, authorizes the FDA to exempt drugs from the requirement that a drug bear adequate directions for use where it "is not necessary for the protection of the public health."

Since 1938, the FDA has recognized that some animal drugs cannot be used safely except under a veterinarian's supervision, and that such drugs, by definition, cannot be labeled adequately for laymen's use. Such drugs nonetheless can be of great medical benefit when used under the direction of a licensed health professional. Thus, rather than ban the drugs as misbranded, the FDA has exempted them under the proviso to Section 502(f) so long as they are sold pursuant to a veterinarian's prescription or other order. The agency's rationale is that "adequate directions for use" are not "necessary" because the veterinarian's directions protect the public health. The result of this policy is that many useful veterinary drugs are now available which otherwise would have to be withdrawn.[4]

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[4] Nearly half of the roughly 1200 veterinary drugs for which the agency has approved New Animal Drug Applications (see 21 U.S.C. 360b) are labeled for use only by or on

Current FDA regulations specify essentially three relevant conditions for an exemption. First, the drugs must be distributed by persons who are "regularly and lawfully engaged in" the handling of such drugs. 21 C.F.R. 201.105(a)(1). Second, the drugs must be "sold only to or on the * * * order of" a licensed practitioner for use in his professional practice (*ibid.*). And third, the drugs must bear, inter alia, a legend stating: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." 21 C.F.R. 201.105(b)(1). Veterinary drugs which can be used properly only under the supervision of a veterinarian, but which do not satisfy all three conditions for an exemption, are misbranded, because they do not and cannot bear adequate directions for lay use.

2. On November 3, 1978, the government brought suit in the United States District Court for the Northern District of Ohio, seeking to enjoin petitioner Colahan and his dealers[5] from the distribution of various veterinary prescription drugs without a prescription or other veterinarian's order, in violation of Section 301 of the FDCA, 21 U.S.C. 331 (Pet. App.

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the order of a veterinarian. Included are narcotics, barbiturates, anesthetics, anticonvulsants, hormones (including steroids), stimulants, and tranquilizers.

[5] Petitioners IBA, Inc., a Massachusetts corporation, and Daniel J. Belsito, President of IBA, market veterinary prescription drugs through franchised distributors located across the United States. These distributors, in turn, sell the drugs to IBA dealers (route salesmen), who retail the drugs. Most of the IBA customers are dairymen and other farmers. Petitioner Jerry J. Colahan, doing business as IBA of Ohio, is the IBA distributor in Ohio. His co-petitioners are IBA dealers who receive their drugs from him.

A2).[6] All but two of the drugs had been approved by the FDA through action on a NADA that had been submitted by the drug's manufacturer. On November 3, 1978, the district court entered a temporary restraining order prohibiting petitioners from distributing misbranded drugs. Shortly thereafter, the court entered a stipulated order pursuant to which the defendants agreed not to distribute nine named drugs except on a veterinarian's prescription until further order by the court. *Id.* at A3, A27.[7]

On October 9, 1979, the district court held that FDA lacked statutory authority to promulgate 21 C.F.R. 201.105, under which FDA regulated veterinary prescription drugs, and the court dissolved the stipulated order (Pet. App. A58-A66). The government appealed, and the court of appeals reversed the district court's ruling, concluding that FDA possessed the statutory authority to restrict certain veterinary drugs to use by or on the prescription or other order of a veterinarian (*id.* at A49-A57; 635 F.2d 564). This Court denied certiorari. 454 U.S. 831 (1981).

3. On remand, the district court ruled that petitioners had violated 21 U.S.C. 331 and 352, and 21 C.F.R. 201.105, by engaging in the retail distribution

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[6] Section 301(a) of the Act, 21 U.S.C. 331(a), prohibits the introduction or delivery for introduction into interstate commerce of any misbranded drug. Section 301(k), 21 U.S.C. 331(k), prohibits the doing of any act to any drug while held for sale after shipment in interstate commerce which results in the drug's being misbranded.

[7] On August 16, 1979, the government brought a separate action against petitioner IBA in the United States District Court for the District of Massachusetts. That case was ultimately transferred to the Northern District of Ohio and was consolidated with the earlier action. Pet. App. A35.

of misbranded veterinary drugs (Pet. App. A29-A48). At the outset, the court noted that the FDA had approved 14 of the drugs at issue as new animal drugs[8] and had required a cautionary prescription legend as a condition of its approval (*id.* at A33). The court ruled that FDA has primary jurisdiction to make such determinations and that a district court could not review the agency's decision regarding the prescription status of the drugs (*id.* at A37-A39). The district court explained that Congress granted the FDA primary jurisdiction over the determination whether to approve the interstate distribution of new animal drugs, and that allowing parties such as petitioners to challenge the FDA's determination of the prescription status of the drugs would be inconsistent with the congressional scheme (*id.* at A37-A38).[9]

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[8] The 14 new animal drugs are listed at Pet. App. A6 n.2 & A29-A30. The district court's ruling also included a fifteenth such drug, but the court later excluded that drug from the scope of its injunction on a stipulation by the parties that the drug could be purchased over the counter without a prescription (*id.* at A27-A28).

[9] The court added that a district court may determine whether a caution legend is unnecessary when the FDA has not considered the question whether a given drug is a new animal drug (Pet. App. A38). In that circumstance, however, a district court could determine only whether there is a general recognition among experts that a given drug is safe and effective, rather than whether the drug is in fact safe and effective, for example, for over-the-counter sale, which is for the agency to determine in the NADA process (*id.* at A38-A39). In this case, the FDA had previously considered the question whether 14 of the products at issue were "new animal drugs," since the agency had approved NADAs for them.

With regard to two drugs not previously approved by the FDA, the court held that one drug could not be dispensed without a prescription above a particular unit dosage, and

Moreover, the court concluded that a drug which can be dispensed only by prescription cannot bear "adequate directions for [lay] use" within the meaning of 21 U.S.C. 352(f) (Pet. App. A40-A41). Finally, the district court found that the "slip system" used by petitioners did not amount to a "prescription or other order of a licensed veterinarian" within the meaning of 21 C.F.R. 201.105 (Pet. App. A41-A43).[10] Petitioners' order forms were inadequate, the court found, because they did not require that a veterinarian authorize the distribution of a prescription drug (*id.* at A42-A43).

4. The court of appeals affirmed the district court in all respects (Pet. App. A1-A23). The court held that the government is entitled to rely on the determination in the premarketing, NADA approval process that a drug cannot be safely distributed without a veterinarian's prescription (*id.* at A10-A13). The court also held that petitioner's distribution system did not comply with 21 C.F.R. 201.105 (Pet. App. A14-A16).

ARGUMENT

The court of appeals' decision is correct and does not conflict with any decision of this Court or of any other court of appeals. Accordingly, review by this Court is not warranted.

1. Petitioners contend that they are entitled to challenge the FDA's administrative determination

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the other drug could not be dispensed at all without a prescription (Pet. App. A44-A47). The court of appeals affirmed that ruling (*id.* at A13), and petitioners have not challenged it in this Court (see Pet. I).

[10] A copy of the "slips" used by petitioners is reprinted in the district court's opinion at Pet. App. A42.

made in the new animal drug application (NADA) process that the drugs at issue may not be distributed in interstate commerce without a prescription from a licensed veterinarian. That contention lacks merit, for several reasons.

First, when Congress has provided an agency with primary jurisdiction over a matter within its expertise, a party may not circumvent the administrative process by seeking to overturn the agency's action in district court. See, *e.g.*, *Whitney Nat'l Bank* v. *Bank of New Orleans & Trust Co.*, 379 U.S. 411, 421-422 (1965). The FDA has the exclusive jurisdiction whether to approve a NADA and under what conditions a new animal drug may be used—*i.e.*, to determine whether and under what conditions a drug is safe and effective for each of its intended uses. The FDA's determination is subject to review in the court of appeals, but its decision must be upheld if it is supported by substantial evidence. See 21 U.S.C. 355(h), 360b(h); *Ciba Corp.* v. *Weinberger*, 412 U.S. 640, 643-644 (1973); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 626; *Rutherford* v. *United States*, 806 F.2d 1455, 1461 (10th Cir. 1986); *Neo-Terra*, 725 F.2d at 978-981; *United States* v. *Undetermined Quantities of Various Articles of Drug*, 675 F.2d 994, 1000 (8th Cir. 1982), cert. denied, 460 U.S. 1051 (1983); *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F.2d 795, 801-804 (2d Cir. 1980).[11] Moreover, the FDA

[11] By contrast, the district courts share with the FDA the jurisdiction to determine whether a drug is in fact a "new animal drug" subject to the FDCA if the FDA brings an enforcement action against an unapproved drug. 21 U.S.C. 321(w); *Neo-Terra*, 725 F.2d at 980-981; *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F.2d 795, 801

has the exclusive authority to modify the conditions of use specified in a NADA, subject to review in the court of appeals under a substantial evidence standard. See 21 U.S.C. 360b(e)(1)(E), 360b(m)(4)(A)(ii); *American Cyanamid*, 770 F.2d at 1216-1218.[12] Put another way, the FDA has the exclusive authority to determine whether a drug can be sold over-the-counter or only by prescription, and whether to modify that decision. The district court therefore lacks the authority to undertake the inquiry proposed by petitioners.

Petitioners' proposed interpretation of the Act would lead to serious disruption of the regulatory scheme. Drug manufacturers have two alternative routes to market animal drugs: they can seek FDA approval of the drug, or they can market the drug without FDA approval on the assumption that the product is not a "new animal drug" subject to the FDCA. *E.g.*, *Neo-Terra*, 725 F.2d at 981. Petitioners' construction of the Act would provide the distributors of a drug with greater rights than the drug's manufacturers, because under petitioners' interpretation, distributors could at any time obtain de novo review in district court of the FDA's determination regarding the prescription status of a drug,

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(2d Cir. 1980). In that case, however, the question before the district court is not whether the drug in fact is safe and effective for each of its intended uses, but is whether the drug is "generally recognized" by qualified experts as safe and effective for each such use. 21 U.S.C. 321(w); *Neo-Terra*, 725 F.2d at 980-981.

[12] A change in the conditions of use, including a change in the marketing status of an approved drug, is accomplished by FDA action on a supplemental NADA. 21 U.S.C. 306b(e)(1)(E).

even though the sponsors of that drug are limited to seeking timely review in the courts of appeals under a more restricted standard of review. Alternatively, petitioners' construction of the Act would allow the sponsors of a drug to obtain de novo review in district court of the FDA's prescription status decision simply by refusing to market the drug under the conditions approved by the FDA. Moreover, permitting the marketing status (*i.e.*, prescription or over-the-counter status) of a drug to be challenged in an enforcement action in district court would also create considerable uncertainty as different courts resolved this question in a different manner. See *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 626 ("[o]nly paralysis would result if case-by-case battles in the courts were the only way to protect the public against unsafe or ineffective drugs"). Finally, allowing such challenges would enable parties such as petitioners to challenge a condition on the use of a drug in an action in which the drug's sponsor is not a participant.

Contrary to petitioners' suggestion (Pet. 11-12), the court of appeals did not at all rely on collateral estoppel principles as a basis for its decision. Petitioners also erroneously assert (Pet. 11) that they have no opportunity to participate in the administrative process by which drugs are approved as prescription drugs. Parties such as petitioners, who disagree with a drug's prescription status, can file a citizens petition with the FDA seeking an amendment to the order approving a NADA. See 21 C.F.R. 10.25. If the FDA declines to amend its order, the agency's decision is subject to judicial review. See 21 C.F.R. 10.45(d). Petitioners can also encourage the sponsors of the drugs they wish to distribute to submit a

supplemental application to the agency seeking a change in the marketing status of the drugs. All that the court of appeals has held is that petitioners cannot circumvent the system devised by Congress and implemented by FDA by challenging the prescription status of drugs in an enforcement action.

The court of appeals' decision does not conflict with any of the decisions cited by petitioners. *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), held only that a district court lacks jurisdiction to enjoin multiple seizures in actions brought by the FDA under the Act. *Ciba Corp.* v. *Weinberger*, held that a drug's sponsor may not challenge in district court the FDA's determination in the NADA process that the drug is a new drug subject to the FDCA (412 U.S. at 643-644). Finally, none of the lower court decisions cited by petitioners ruled that a district court has jurisdiction to determine whether a new animal drug is safe and effective for its intended use, or to approve a change in the conditions under which the FDA has approved the use of a drug. Rather, those decisions simply recognize that a district court has concurrent jurisdiction with the FDA to determine whether a product is a "new drug"—*i.e.*, whether it is "generally recognized" as safe and effective (21 U.S.C. 321(w))—only if the agency has not already made that determination. See *Ciba Corp.* v. *Weinberger*, 412 U.S. at 643-644.[13] In this case, how-

[13] See *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F.2d at 801-805; *United States* v. *X-Otag Plus Tablets*, 602 F.2d 1387 10th Cir. 1979); *United States* v. *Articles of Drug*, 585 F.2d 575, 582-583 (3d Cir. 1978). The only other circuit case cited by petitioners involved an unapproved product, a device, which the court found to be misbranded under 21 U.S.C. 352(f), rather than a drug. *United*

ever, both the new animal drug status and the conditions of approval have previously been decided by the FDA. None of the decisions cited by petitioner suggests that a district court may reconsider the FDA's determinations.

2. Petitioners refer in their questions presented (Pet. I) to the court of appeals' ruling that their sales practices violated 21 C.F.R. 201.105, but petitioners do not develop that argument in their petition. In any event, that factbound question does not warrant further review. The FDA's interpretation of its own regulations is entitled to considerable deference from the courts (*e.g.*, *Luckhard* v. *Reed*, No. 85-1358 (Apr. 22, 1987), slip op. 9, 12 (plurality opinion); *Lyng* v. *Payne*, No. 84-1948 (June 7, 1986), slip op. 12-13), and, as the courts below explained (Pet. App. A14-A16, A42-A43), the agency's interpretation is eminently reasonable. The agency's regulation is designed to ensure that prescription animal drugs will be dispensed only at the direction of a licensed veterinarian, and petitioners' order forms (see Pet. App. A42 (reprinting form)) do not provide assurance that drugs will be dispensed only in those circumstances.

States v. *Article of Device*, 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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JULY 1987

☆ U. S. GOVERNMENT PRINTING OFFICE: 1987 181483 40424